K011125

JUN 1 3 2001

SECTION 20

510(K) SUMMARY

Hudson RCI Over the Counter Nasal Cannula
Section 20

1.0 Date

April 5, 2001

2.0 Submitter

Hudson Respiratory Care, Inc.
27711 Diaz Road
Temecula, California 92590

3.0 Contact Person

Jeannie L. Denning ASQ CQA

4.0 Telephone

(909) 676-5611, ext. 1232

5.0 Proprietary Device Name

Hudson RCI Over the Counter Nasal Cannula

6.0 Classification Name

Oxygen, Nasal Cannula

7.0 Common Name

Nasal Cannula

8.0 Predicate Device

Hudson RCI Over the Ear Cannula, K 770487

9.0 Device Description

Hudson RCI Over the Counter Nasal Cannula are designed for use with patients that are in need of low flow supplemental oxygen in home care, outpatient care centers, extended care facilities or hospital environments. The Hudson RCI Over the Counter Nasal Cannula is comprised of a soft plastic tube with two prongs which fit into the nose. The Cannula is held in place with two small diameter pieces of tubing which fit over the ears, and can be tightened by means of a plastic slide under the chin. Hudson RCI currently sells nasal Cannula with a variety of lengths of supply tubing which connect the product with an oxygen supply source. Hudson RCI Nasal Cannula are also sold without supply tubing.

10.0 Intended Use

Hudson RCI Over the Counter Nasal Cannula are intended to be a conduit for providing low flow oxygen to patients who need supplemental oxygen therapy.

12.0 Comparison of Technological Characteristics

The Hudson RCI Over the Counter Nasal Cannula and the predicate nasal Cannula are identical in design, materials, and performance. The only difference between the proposed over the counter devices and the predicate devices is that the product labeling has been written for use by the Lay user.

13.0 Conclusion

Hudson RCI Over the Counter Nasal Cannula are substantially equivalent to the predicate devices, in that they are identical in design, function, performance, materials of composition and intended use. Both the predicate and the proposed devices are intended for use in home care, outpatient care centers, extended care facilities or hospital environments. The only difference between the proposed over the counter nasal Cannula and the predicate nasal Cannula, is that the product labeling has been written for use by the lay user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 3 2001

Ms. Jeannie Denning
Hudson Respiratory Care, Inc.
27711 Diaz Road
P.O. Box 9020
Temecula, CA 92589-9020

Re: K011125
Nasal Cannula
Regulation Number: 868.5340
Regulatory Class: I (one) exempt
Product Code: 73 CAT
Dated: April 9, 2001
Received: April 13, 2001

Dear Ms. Denning:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

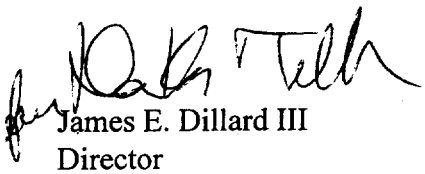
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if Known): K011125

Device Name: Hudson RCI Over the Counter Nasal Cannula

Indications for Use:

The Hudson RCI Over the Counter Nasal Cannula is used to provide low flow oxygen to patients who need supplemental oxygen therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011125

Over the Counter Use Only